

REMARKS

With this response, applicants have amended the previously pending claims to emphasize those features of the invention that are in part responsible for the commercial success and widespread acclaim of products that embody those features, and to clarify the significant differences between the claimed product and the cited art.

Claims 1-4, 6, and 47 have been amended, claims 5, 23-25, 27, 28, 30-45, 48-75, and 77-100 have been canceled, and new claims 101-109 have been added. Upon entry of this Submission, then, claims 1-4, 6-22, 26, 29, 46, 47, 76, and 101-109 will be pending, with claims 9-11 and 14-22 having been withdrawn as directed to a nonelected species and claim 76 having been withdrawn as directed to a nonelected invention.

Reconsideration of the application is respectfully requested in light of the present amendments, the discussion that follows, and the accompanying Declaration Under 37 C.F.R. §1.132.

The Amendments:

Claim 1 has been amended to clarify the invention. Representative sources of support for the changes that have been made are as follows (the paragraph numbers identifying representative sources of support in the specification correspond to the paragraph numbers in the published patent application, U.S. 2004/0247669 A1, and not to the paragraph numbers in the patent application as filed):

“approximately 25 wt.% to 49.5 wt.%”: ¶ 0034

“micronized ethylcellulose”: ¶ 0039

“solution viscosity in the range of 1 cP to 120 cP”: ¶0040, claim 5 as filed

“admixed”: ¶0007

“weight ratio of approximately 1:1.5 to 1.5:1”: claim 21 as filed

“soft”: ¶0011

“pliable”: ¶0103

“gradually erodes in the mouth”: throughout; see, e.g., Examples 16-18

“gradually releasing the flavoring agent”: ¶0007

“extended time period”: ¶0031

The amendments to claims 2 -4 reflect the change in terminology in claim 1 regarding the extended time period.

Claim 5, made redundant by the amendment to claim 1 (regarding solution viscosity of the micronized ethylcellulose), has been canceled.

Claim 6 has been amended to update antecedent basis in light of applicants' cancellation of claim 5 and amendment to claim 1 regarding “micronized ethylcellulose.” Claim 7 has been amended in a similar manner.

Claim 8 has been amended to refer to claim 8, as was originally intended.

Claims 21-25, made redundant by the incorporation of the ethylcellulose:flavoring agent weight ratio, have been canceled.

Claims 26 and 29 have been amended to simplify the recitation of the sweetener. Claims 27 and 28 have been canceled, and new claim 101 has been added, directed to the preferred sweetener, xylitol.

Claims 30-45, directed to a non-elected invention (chewing gum), have been canceled.

The dependency of claim 47 has been changed in light of applicants' cancellation of claim 30.

Nonelected claims 48-75, drawn to lozenges having a beneficial agent in addition to the flavoring agent, have been canceled. Nonelected claims 77-99, drawn to methods of using such lozenges, have also been canceled, as has claim 100.

Nonelected claim 76 has not been canceled, but, rather, has been amended to reflect some of the changes in terminology made in claim 1.

New claim 102 specifies the ethoxyl content of the micronized ethylcellulose as being in the range of about 45.0% to 52.0%, as set forth in ¶0040.

New claims 103 and 104 pertain to the particle size of the micronized ethylcellulose, as described in the specification at the end of ¶0039.

New claims 105-107 specify the solution viscosity of the ethylcellulose as being in the range of approximately 90 to 110 cP, as set forth in the specification in ¶0040.

New claim 108 specifies the amount of additive as being in the range of about 1 wt.% to about 45 wt.%; see ¶0034.

New claim 109 is a product-by-process claim, and finds support, for example, in ¶0096.

Accordingly, all amendments and new claims are fully supported by the original disclosure, and entry thereof is thus proper.

Rejections Under 35 U.S.C. §112:

In the final Action, claim 100 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, and under 35 U.S.C. §112, second paragraph, as indefinite. These rejections are now moot in light of applicants' cancellation of claim 100. Claim 12 was also rejected as indefinite due to an inadvertent typographical error; the claim has now been corrected.

Withdrawal of the rejections under 35 U.S.C. §112 is thus in order.

Rejections Under 35 U.S.C. §103:

Claims 1-8, 12, 13, 23-25, 30, 46-48, 72 and 83 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,528,125 to Alderman et al. ("Alderman"), and claims 26, 28, 29, and 55-57 were separately rejected under 35 U.S.C. §103(a) as obvious over Alderman combined with U.S. Patent No. 6,183,775 to Ventouras ("Ventouras"). Alderman has been cited as pertaining to a composition containing ethylcellulose and an essential oil, while Ventouras has been cited for its teaching regarding sweeteners. These rejections are addressed in part by the present amendments, in part by the accompanying declaration, and are otherwise traversed.

As applicants have stated previously, Alderman discloses a method for making a particulate or film composition using a process that involves: (1) preparing an aqueous dispersion of (a) a polymer, (b) a fragrance or flavor, and (c) a suspending agent that facilitates dispersion; (2) heating the dispersion to facilitate diffusion of the organic flavor or fragrance from the aqueous vehicle into the polymer particles; and (3) spraying, dewatering, or otherwise forming a dry final product from the mixture. See column 6, lines 1-53. Alderman states that

the suspending agent is optional and may be omitted with smaller particles and/or high viscosity dispersions (column 2, lines 52-59).

The Examiner has given the term “matrix” an unduly broad meaning relying on a dictionary definition. In the final Action (at pp. 4-5), the Examiner states that an aqueous dispersion of ethylcellulose containing an essential oil could in fact be construed as a “wet matrix,” as could the aqueous liquid in the aqueous dispersion. While applicants disagree with the Examiner's interpretation here, particularly the statement that an aqueous dispersion can be viewed as a matrix, the claims as presently amended distinguish over the prior art on account of other limitations.

That is, claim 1 now specifies the dosage form as a lozenge in the form of a sustained release matrix that is soft and pliable, a characteristic believed to result from the weight ratio of the polymer (micronized ethylcellulose) to the flavoring agent, the admixture of the two components, and the relative quantity of each (25 wt.% to 49.5%) in the matrix composition. The soft, pliable matrix allows for gradual release of the flavoring agent over an extended time period, e.g., at least 15 minutes, as the lozenge gradually erodes in the mouth.

The attached Declaration Under 37 C.F.R. §1.132 emphasizes the distinctions over Alderman. In that Declaration, executed by one of the co-inventors, Jerry Gin (who is also the co-founder and CEO of the company to which the present application is assigned), a composition is prepared using the Alderman technique as described in Example 1 of that patent. As Dr. Gin found, the Alderman composition had become crisp and hard, with only a faint flavor, and the feel of hard plastic in the mouth. It is Dr. Gin's opinion that the Alderman product could be formed into a lozenge only if it were ground up and the particles so provided compressed into a hard tablet. This, in turn, means that the dried Alderman composition could not be made into a soft, sustained release matrix as claimed; rather, as Dr. Gin notes, the Alderman composition could only be incorporated as an ingredient in an insoluble tablet.

In sum, Alderman does not teach how to achieve the claimed characteristics of softness, pliability, and gradual erosion in the mouth. Neither does Alderman teach the composition

ranges recited in claim 1 as presently amended. For this reason, there is no prima facie case of obviousness of claim 1 over Alderman.

In addition, even if there were a prima facie case of obviousness to answer, it is necessary to consider evidence of secondary considerations which support a conclusion of non-obviousness. “It is the secondary considerations that are often most probative and determinative of the ultimate conclusion of obviousness or nonobviousness.” *Pro-Mold & Tool Co. v. Great Lakes Plastics Inc.*, 75 F.3d 1568 (Fed. Cir. 1996). “Office personnel should consider all rebuttal arguments and evidence presented by applicants. Rebuttal evidence may include evidence of secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others.” MPEP § 2145 (citations and internal quotation marks omitted).

The attached Declaration also provides information regarding secondary considerations. In particular, paragraphs 11-15 of the declaration describe how a product within the scope of the invention has been praised by others (paragraph 11). The product has been commercially successful since its launch in May 2008 (paragraph 13). The commercial success is believed due to characteristics of the product which are presently recited in claim 1 and the absence of a prior commercial product with those characteristics (paragraphs 12 and 14). Thus, the two secondary considerations of praise of others and commercial success support a conclusion that the claims as presently amended are non-obvious.

If the Examiner has any questions concerning this communication, it is respectfully requested that she contact the undersigned attorney.

Respectfully submitted,

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